

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOSTON SCIENTIFIC CORPORATION)
and BOSTON SCIENTIFIC SCIMED,)
INC.,)

Plaintiffs/Counterclaim)
Defendants,)

v.)

Civil Action No. 15-980-LPS-CJB

COOK GROUP INCORPORATED and)
COOK MEDICAL LLC,)

Defendants/)
Counterclaimants.)

REPORT AND RECOMMENDATION

In this action filed by Plaintiffs/Counterclaim Defendants Boston Scientific Corporation (“BSC”) and Boston Scientific SciMed, Inc. (“BSSI”) (collectively, “Plaintiffs” or “Boston Scientific”) against Defendants/Counterclaimants Cook Group Incorporated and Cook Medical LLC (collectively, “Defendants” or “Cook”), Plaintiffs allege infringement of United States Patent Nos. 8,685,048 (the “048 patent”), 8,709,027 (the “027 patent”), 8,974,371 (the “371 patent”), and 9,271,731 (the “731 patent”) (collectively, the “asserted patents” or the “patents-in-suit”). Presently before the Court is the matter of claim construction. The Court recommends that the District Court adopt the constructions set forth below for the seven terms/term sets discussed in this Report and Recommendation.¹

¹ The parties originally submitted 13 terms or sets of terms for claim construction, (D.I. 54; D.I. 62), for which they provided argument in their claim construction briefing. Prior to the *Markman* hearing, Defendants withdrew the term set “operably associated with / coupled to the control member” from the list of terms/term sets to be construed. (D.I. 66) After the *Markman* hearing, the parties also agreed to the following constructions of two previously disputed claim terms/term sets:

I. BACKGROUND

A. The Parties

BSC is a Delaware corporation with its principal place of business in Marlborough, Massachusetts. (D.I. 19 at ¶ 2) It develops, manufactures, and supplies medical devices, including endoscopic products for the treatment of diseases of the digestive system. (*Id.*) BSSI is a Minnesota corporation with its principal place of business in Maple Grove, Minnesota. (*Id.* at ¶ 3) It is the wholly owned subsidiary of BSC, and it develops and manufactures endoscopic products, including hemostatic clips distributed by BSC. (*Id.*) BSSI is the owner by assignment of the patents-in-suit. (*Id.*)

Cook Group Incorporated is an Indiana corporation with its principal place of business in Bloomington, Indiana. (*Id.* at ¶ 4) It is alleged to be a major competitor of Plaintiffs in the endoscopic hemostatic clip market. (*Id.* at ¶ 15) Cook Medical LLC is an Indiana limited liability company with its principal place of business in Bloomington, Indiana. (*Id.* at ¶ 5) It is also alleged to be a major competitor of Plaintiffs in the endoscopic hemostatic clip market, and has sold the Instinct™ Endoscopic Hemoclip since at least 2013. (*Id.* at ¶ 15; D.I. 52 at 4)

B. The Asserted Patents

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1. “at an area of the sheath” means “within the lumen or wall of the sheath”
 2. “outer sleeve” / “a sleeve” / “the sleeve” means “a sleeve structure that is separate and distinct from the structures that make up the clip”

(D.I. 68) Of the ten remaining terms or sets of terms, three involve consideration of caselaw relating to means-plus-function claiming; the Court will address those three terms together in a separate, forthcoming Report and Recommendation.

The patents-in-suit describe and claim endoscopic clips for use inside the body.

Three of the four asserted patents (the '048, '027, and '731 patents) (the “Adams patents”) are entitled “Device and Method for Through the Scope Endoscopic Hemostatic Clipping”; they share substantially identical specifications. (D.I. 54, exs. B-D)² The Adams patents relate to “compression clips used to cause hemostasis of blood vessels located along the gastrointestinal tract delivered to a target site through an endoscope.” ('048 patent, col. 1:21-23) Essentially, the claimed invention makes up an apparatus and technique for endoscopists to treat gastrointestinal bleeding without the need for surgery and its associated risks. (*See id.*, cols. 1:27-34, 2:50-57) According to the patents, the invention’s “key advantages” include “[t]he device’s ability to repeatedly open and close the clip[.]” the ease with which the device can be rotated in certain embodiments, and the fact that, in certain embodiments, “the device is completely set up, with the clip already attached to the delivery device, unlike the competing device.” (*See id.*, col. 3:5-20) These features are asserted to improve the success rate of procedures, reduce the time required to perform procedures, and allow for a device that is easier to use. (*Id.*)

The '371 patent (or “Durgin Patent”) is entitled “Through the Scope Tension Member Release Clip” and claims an “apparatus for applying clips to tissue[.]” ('371 patent, col. 16:59) Aside from the fact that it does not claim a method, the Durgin Patent differs from the Adams patents in that it describes an assembly designed to provide multiple stages of “feedback” to the physician during the procedure. (*See id.*, cols. 1:44-62, 9:43-64) This feedback allows the user, *inter alia*, to be “certain of the status of the” clip assembly during the deployment operation,

² The asserted patents appear on the docket in this action more than once. Citations to the patents will simply be to the '048 patent, the '027 patent, the '371 patent, and the '731 patent.

reducing the likelihood of deployment of a clip at an incorrect location. (*Id.*, cols. 1:33-35, 9:37-39)

C. Procedural Posture

Boston Scientific commenced this action on October 27, 2015, alleging that Cook infringed three of the patents-in-suit (all but the '731 patent). (D.I. 1) On January 29, 2016, Chief Judge Leonard P. Stark referred this case to the Court to hear and resolve all pre-trial matters, up to and including the resolution of case-dispositive motions.

Boston Scientific filed an Amended and Supplemental Complaint for Patent Infringement as to all four patents-in-suit on March 9, 2016. (D.I. 19) On July 15, 2016, Cook filed its Amended Answer and Counterclaims seeking declaratory judgments of non-infringement and invalidity of each of the asserted patents. (D.I. 52)

The parties filed simultaneous opening claim construction briefs on August 3, 2016, and simultaneous responsive briefs on August 31, 2016. (D.I. 56, 57, 60, 61) The Court held a *Markman* hearing on October 12, 2016. (D.I. 67 (hereinafter "Tr."))

II. STANDARD OF REVIEW

It is well-understood that "[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a generally a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015).

The Court should typically assign claim terms their "ordinary and customary

meaning[,]” which is “the meaning that the term[s] would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citations omitted). However, when determining the ordinary meaning of claim terms, the Court should not extract and isolate those terms from the context of the patent, but rather should endeavor to reflect their “meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321; *see also Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).

In proceeding with claim construction, the Court should look first and foremost to the language of the claims themselves, because “[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips*, 415 F.3d at 1312 (internal quotation marks and citations omitted). For example, the context in which a term is used in a claim may be “highly instructive.” *Id.* at 1314. In addition, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable” in discerning the meaning of a particular claim term. *Id.* This is “[b]ecause claim terms are normally used consistently throughout the patent, [and so] the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Id.* Moreover, “[d]ifferences among claims can also be a useful guide[,]” as when, for example, “the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15.

In addition to the words of the claims, the Court should look to other intrinsic evidence. For example, the Court should analyze the patent specification, which “may reveal a special

definition given to a claim term . . . that differs from the meaning [that term] would otherwise possess.” *Id.* at 1316. In that case, “the inventor’s lexicography governs.” *Id.* Even if the specification does not contain a special definition of the term at issue, it “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.* at 1315 (internal quotation marks and citation omitted). That said, however, the specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). A court should also consider the patent’s prosecution history, if it is in evidence, because it “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]” *Phillips*, 415 F.3d at 1317.

Extrinsic evidence, “including expert and inventor testimony, dictionaries, and learned treatises[.]” can also “shed useful light on the relevant art[.]” *Id.* (internal quotation marks and citations omitted). Overall though, while extrinsic evidence may be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* (internal quotation marks and citations omitted); *accord Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980-81 (Fed. Cir. 1995).

In utilizing these resources during claim construction, courts should keep in mind that “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

III. DISCUSSION

The Court takes up the seven disputed terms/term sets addressed herein in the order in which they were argued.

A. “a control element including a connector element”

The term “a control element including a connector element” appears in claim 11 of the Durgin Patent. (’371 patent, col. 18:10) Claim 11 claims “[a]n apparatus for applying clips to tissue within a living body[.]” (*Id.*, col. 18:1-2) The “control element . . . remains outside the body accessible to a user” during endoscopic procedures, and is connected to a hemostatic clip assembly by the connector element. (*Id.*, col. 18:10-14) Ultimately, once the clip is in place at the target site, the control element “detaches from the connector element” and the clip assembly “via a frangible link[.]” (*Id.*, col. 18:14-15)

The parties’ primary dispute as to this term focuses on the meaning of the word “including.” (*See* D.I. 56 at 25-27; D.I. 57 at 20-21; D.I. 60 at 17 n.10; D.I. 61 at 16; Tr. at 10-59) Defendants assert that the word “including” demands that “the control element and connector element are elements of a single, unitary structure.” (D.I. 54 at 19) Plaintiffs reject this proposal, arguing that the plain meaning of “including” does not necessarily require a unitary structure. (*See, e.g.*, D.I. 57 at 20)

1. The Claim Language

The Court starts first with the claim language, and here the patent’s drafters chose to incorporate into the term the word “including”—a commonly understood word that does not, in and of itself, *require* a single or unitary structure. *Cf. Atl. Constr. Fabrics, Inc. v. Dandy Prods., Inc.*, 64 F. App’x 757, 761 (Fed. Cir. 2003) (holding that the term “filter including an elongated porous material” did not require the “filter” and “porous material” to be a single or unitary

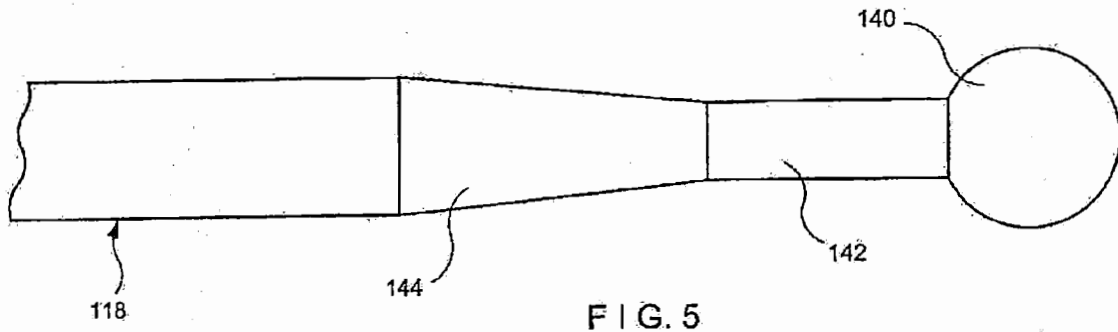
structure). Much of Defendants' argument here is that the patentee clearly and unequivocally disclaimed the ordinarily broad scope of "including," and that the patent instead clearly indicates that a single, unitary structure is required by the term at issue. (*See, e.g.*, Tr. at 12-20, 44-57)³

In making this argument, Defendants rely both on the specification and the prosecution history. The Court assesses both sets of evidence below.

2. The Specification

Defendants first point to the summary of the Durgin Patent, which identifies a "ball connector of a control element of the delivery device to maintain the clip assembly coupled to the delivery device," ('371 patent, col. 1:57-59), arguing that said "ball connector" constitutes the "connector element[.]" (D.I. 56 at 27; Tr. at 11-12, 18-19). If this is the case, Defendants assert, then the specification and figures repeatedly depict this example of a "control element including a connector element" as one unitary structure. (*See, e.g.*, '371 patent, cols. 4:52-54 ("As shown in FIG. 5, the distal end of the control wire 118 ends in a ball 140 which is used to connect the control wire 118 to the appropriate elements of the clip assembly 106"); 7:12-13 ("The ball 140 formed at the distal end of the control wire . . .")) The example is depicted as follows in the patent:

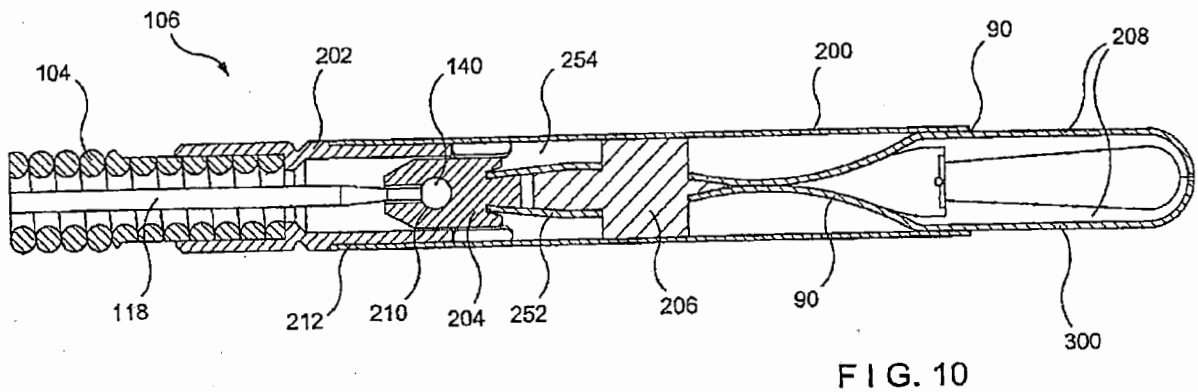
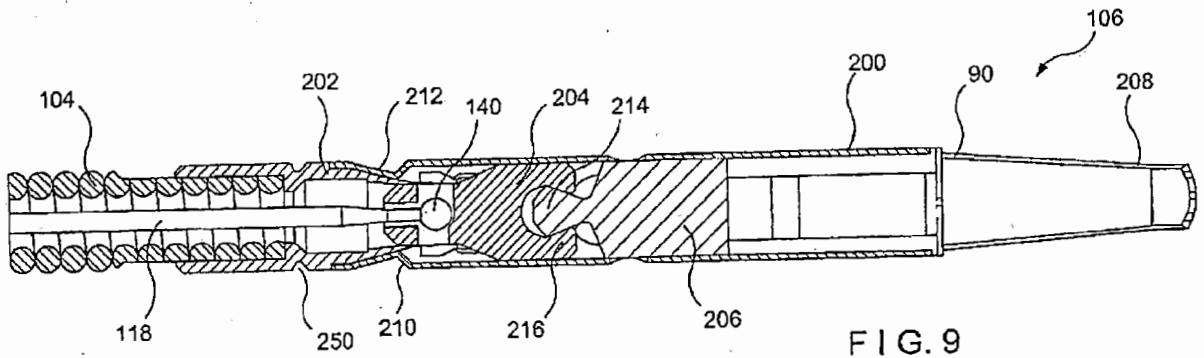
³ Defendants point to *Toro Co. v. White Consolidated Industries, Inc.*, 199 F.3d 1295 (Fed. Cir. 1999) as an analogous case. (D.I. 56 at 27; Tr. at 44, 48) In *Toro*, the United States Court of Appeals for the Federal Circuit construed the phrase "cover including means for increasing the pressure" to mean that the means for increasing the pressure (a "restriction ring") was "permanently affixed to and included as part of the cover." *Toro*, 199 F.3d at 1302. However, in doing so, it acknowledged that the "dictionary definition[] . . . of 'including' [did] not shed dispositive light" on the proper construction of the phrase. *Id.* at 1300. Rather, it found that "including" had the more restricted meaning proffered by the defendant only "in the context of the specification and drawings." *Id.* at 1301. And so, *Toro* underscores that absent a more limiting meaning suggested by the specification or prosecution history, the claim's use of the word "including" here would not necessarily *mandate* a single, unitary structure.



Plaintiffs have at least two counters to this argument.

First, Plaintiffs aptly note that even as to the embodiment utilizing the kind of ball connector described above, the relevant “connector element” may consist of *more* than merely the ball connector itself. (*See* D.I. 60 at 17) The intrinsic support for this assertion comes in part from the “Summary of the Invention” section of the Durgin Patent, which explains that, as to the device described therein, “the control element is frangible to detach the yoke from the delivery device[.]” (’371 patent, col. 1:59-60; Tr. at 29-30 (“So the ball here I think is part of the connector element. And I think the yoke is also part of the connector element.”)) When read in conjunction with the language of claim 11, which states that “the control element detaches from the connector element via a frangible link[.]” (’371 patent, col. 18:14-15), one can see that claim 11’s description of how the control element can interact with (and detach from) the connector element mirrors the “Summary of the Invention” section’s description of how the control element interacts with (and detaches from) the yoke. This suggests that the yoke may constitute at least a part of the connector element. And that, if correct, would cut against Defendants’ proposed construction, because the control wire and the yoke, as depicted in the figures below, do not

appear to be part of a “single, unitary structure.” (*See, e.g.*, '371 patent, FIGS. 9, 10)⁴



Second, even assuming *arguendo* that “connector element” is synonymous with “ball connector,” in this example, it would still not be clear that the specification *requires* the control element and the ball connector to be “elements of a single, unitary structure.” Plaintiffs suggest, and the Court agrees, that the specification does not clearly preclude an embodiment in which the connector element and the remainder of the control element are “structures that are separate but still connected together.” (D.I. 57 at 21) As Plaintiffs correctly note, “the specification is silent

⁴ In both Figures 9 and 10, the control wire is denoted as 118, the ball connector 140, and the yoke 204. ('371 patent, FIGS. 9, 10 & cols. 6:59-7:25)

as to whether the ball connector is formed integrally with the control wire or is separately constructed and subsequently attached to the control wire.” (*Id.*) And so, there is no indication that the patent excludes embodiments in which, for example, a control wire and connector element that are multiple, distinct structures nevertheless “are glued together in the course of manufacturing[,]” are bolted together, or have hooks connecting them. (Tr. at 28)

As such, the specification does not provide a basis for the Court to limit the claims in the manner Defendants suggest.

3. The Prosecution History

Because the specification, for the reasons noted above, does not restrict the meaning of “a control element including a connector element” in a manner favorable to them, Defendants’ argument therefore hinges on the Durgin Patent’s prosecution history. Defendants contend that this history reveals that Plaintiffs “disavow[ed] multi-component control elements.” (D.I. 56 at 26; *see also* D.I. 61 at 16-17) More specifically, Defendants assert that in distinguishing the Durgin Patent from a prior art reference—specifically, U.S. Patent Application No. US 2002/0045909, (D.I. 56, Tab 7), (the “Kimura reference” or “Kimura”)—Plaintiffs disclaimed any meaning of the disputed phrase in which the control element and connector element make up “multiple, distinct structures.” (D.I. 56 at 26 (emphasis omitted); *see also* Tr. at 52-53)

Claim 11 of the Durgin Patent, as originally drafted,⁵ did not include the phrase “including a connector element”; instead, it recited “a control element . . . [having] a distal end removably connected to the clip assembly[.]” (*See* D.I. 54, ex. J, at COOKMED0005460; *see*

⁵ In the relevant portions of the prosecution history discussed here, what is now claim 11 of the Durgin Patent was then referred to as “claim 41.”

also Tr. at 12) The Examiner rejected this claim based on, *inter alia*, the Kimura reference. (*See* D.I. 54, ex. J, at COOKMED0005523-24) Kimura, like the patents-in-suit, describes a device for clipping physiological tissue. (Kimura at [0002]; Tr. at 13) Multiple embodiments of Kimura depict a “manipulating wire” that is analogous to the control wire in the asserted patents. (*See, e.g.*, Kimura at [0141], [0204]) In an illustrative embodiment, when the manipulating wire is retracted, “the fracture section **3d** of the link member **3** of the clip **2** breaks[.]” (*Id.* at [0152]) This description demonstrates that the manipulating wire (the Kimura analog to the “control wire”) is at one point connected to the clip via the “fracture section.”

Yet during prosecution of the Durgin Patent, Plaintiffs argued to the Examiner that “Kimura does not teach or suggest ‘a control element including a connector element . . . removably connected to the clip assembly via the connector element, wherein the control element detaches from the connector element via a frangible link,’ as recited in [now] amended claim 41.” (D.I. 54, ex. J at COOKMED0005547) The Examiner did not accept this argument and rejected claim 41, determining that Kimura disclosed “a control element . . . **including** a connector element[.]” (*Id.*, ex. J at COOKMED0005573-74 (emphasis in original)) In responding to the Examiner’s conclusion, the patentee made the following statement, which Defendants point to as amounting to a clear disavowal of the otherwise broad scope of “including”:

Applicants contend that control element of Kimura is the control wire 7 which is coupled to the proximal end of hook section 12. Because the clip assembly 2 is coupled to the link member [3], the control wire 7 does not have a connector element that is detached via a frangible link and cannot meet the recitation of claim 10.

(D.I. 56 at 11 (citing D.I. 54, ex. J at COOKMED0005582) (emphasis omitted)) In essence,

Defendants are arguing that when the patentee said above that the control element was only “the control wire 7[.]” what the patentee was really conveying is that the control element could not possibly “include” the other identified structures (hook section 12 and link member 3) precisely *because* those structures were *separate and distinct* from the control wire.

And yet, to the Court, it is *not* obvious that in making the above statement, the patentee was intending to clearly communicate that a control element must be a single, unitary structure. It could instead be the case that, as Plaintiffs suggest, (Tr. at 42), the patentee was there intending to distinguish Kimura from the Durgin Patent on the ground that in Kimura “the control wire 7 does not have a connector element *that is detached via a frangible link[.]*” (D.I. 54, ex. J at COOKMED0005582 (emphasis added)) Or there could be some other related, but different point that the patentee was trying to make.

But the important thing is that it is just not *clear* what the patentee was trying to convey. (Tr. at 43 (Plaintiffs’ counsel noting that, as to the above-referenced statement, “[t]he point is this is not clear.”)) And, as Plaintiffs’ counsel correctly noted at the *Markman* hearing, “[t]here is [otherwise] no statement in [the prosecution history] that says any control element of Kimura is different because it has multiple pieces. And there is no statement that says the claimed control element can only be one piece.” (*Id.* at 42) And so, in the Court’s view, Plaintiffs never clearly disclaimed a construction of “a control element including a connector element” made up of multiple, distinct structures.

4. Conclusion

Because Defendants have not shown that the Durgin Patent’s specification or its prosecution history demand its proffered narrowed construction of this term, the Court rejects

Defendants' proposal. This resolves the dispute here between the parties. The Court otherwise recommends that "a control element including a connector element" be afforded its plain and ordinary meaning.

B. "frangible link"

The term "frangible link" is found in dependent claim 4 of the '027 patent and in multiple claims of the Durgin Patent. The '027 patent claims in part a "medical device . . . comprising a frangible link coupling the clip to the control member." ('027 patent, col. 15:53-54) Claim 5 of the Durgin Patent, a dependent claim, claims an "apparatus . . . wherein the control member is coupled to the yoke via a frangible link." ('371 patent, col. 17:21-22) And claim 11 of that patent, which is an independent claim, describes an apparatus in which "the control element detaches from the connector element via a frangible link[.]" ('371 patent, col. 18:14-15)

Defendants propose that "frangible link" should be construed as "a breakable, fragile, or brittle portion of a single, unitary structure designed to fracture into separate pieces." (D.I. 54 at 22) Plaintiffs propose the construction: "a link between at least two components that become unlinked when a tensile load is applied." (*Id.*) The parties do not really dispute that "frangible" means breakable, fragile, or brittle. (D.I. 56 at 27-29; D.I. 57 at 22) Rather, as Plaintiffs put it, "[t]he parties dispute what structure is 'frangible.'" (D.I. 57 at 22) "BSC proposes that the link itself is breakable, *i.e.*, the linked components become unlinked; the components forming the link do not themselves need to be breakable. Cook argues that the link can only be formed from one, unitary piece that must itself be breakable[.]" (*Id.*) Essentially, Defendants seek a construction that would limit "frangible link" to a structure that busts into pieces, while Plaintiffs seek a construction in which a "frangible link" may describe a connection that merely becomes unlinked

under a tensile force, without its components necessarily having to break into pieces.

1. The Claim Language

The claim language, standing alone, is not conclusive, though in the Court's view, it offers Plaintiffs more to work with than it does Defendants.

Plaintiffs point to the fact that claim 4 of the '027 patent recites "a frangible link *coupling the clip to the control member*["] (D.I. 60 at 18) (emphasis in original); they suggest that this phrase demonstrates that the "break" that Defendants argue is required may instead amount to something less than a fracturing (i.e., a mere "decoupling"). And the Court agrees that this reference is of some help to Plaintiffs. Use of the term "coupling" (and what it calls to mind regarding its opposite, a "decoupling") would seem to be a strange word choice, were the frangible link at issue to absolutely require the kind of bursting apart that Defendants suggest.

For their part, Defendants most prominently note claim language that ostensibly indicates that when the patentee:

sought to claim "a link between at least two components that become unlinked when a tensile load is applied," [it] adopted words other than "frangible." For example, BSS adopted the claim terms "releasabl[e]" or "removabl[e]" in the Durgin Patent to claim a relationship between two components that separate or unlink without fracturing a unitary structure into separate pieces.

(D.I. 56 at 28 (citations omitted); *see also* Tr. at 64) And indeed, the Durgin Patent does use the terms "releasably coupled" or "removably connected" in certain claims, to describe how items are connected to the control member or the clip assembly. ('371 patent, cols. 17:8-9, 19-20, 18:18-19, 23-24) But the Court is not willing to afford this fact great meaning as to the claim construction dispute at issue here. Plaintiffs are arguing for a construction for "frangible link"

that includes, *but is not limited to*, the idea of “releasably” or “removably” coupling. If the meaning of “frangible link” (as Plaintiffs suggest) can capture these examples of delinking, but is also broad enough to encompass the type of fracture that Defendants suggest, then the patentee would necessarily have needed to use a term other than “releasably coupled” or “removably connected” in order to suggest this. Thus, the fact that certain claims use “releasably coupled” or “removably connected” is of no moment here.

2. The Specifications

The patents’ respective specifications provide further insight.

The Court first looks to the Durgin Patent’s specification. Defendants assert that therein, the patent “consistently describes the control element as a unitary control wire designed to physically *fracture* into separate pieces—the connector ball from the rest of the wire.” (D.I. 56 at 28 (emphasis in original)) And it is true (and not disputed) that at *certain* points, the Durgin Patent does use such terminology to describe the frangible link. (*See, e.g.*, ’371 patent, cols. 12:43-44 (describing the control wire as being “severed”), 13:5-6 (explaining that after detaching, “the distal end of the control wire **810** may be jagged or sharp.”)) But as Plaintiffs note, at other times, the Durgin Patent specification uses broader wording to describe the link at issue—wording that does not necessarily appear to be limited to the narrowing “fracture” definition supplied here by Defendants. (*See id.*, cols. 1:59-62 (noting, in the Summary of the Invention section, “. . . wherein the control element is frangible *to detach* the yoke from the delivery device and to provide a second user feedback. . . .”) (emphasis added), 15:64-16:1 (“That ball and socket connection includes a ball *detachably coupled* to a body of the control wire”) (emphasis added))

The '027 patent's specification, on the other hand, discloses at least one embodiment that includes a "frangible link" which would clearly not be covered by Cook's proposed construction. The specification describes a component called a "j-hook" that constitutes the frangible link, connecting the control wire to the clip. (*See* '027 patent, cols. 5:44, 7:26-27). In its initial position, the j-hook is inserted into a "cut-out[,] or hole, on the proximal end of the clip. (*Id.*, col. 5:27-28) The j-hook never physically breaks; instead, when a sufficient "tensile load"⁶ is applied to the j-hook, it deforms from a bent position into a straight position and pulls out of the hole to release the clip from the control wire. (*Id.*, col. 7:39-44) Plaintiffs' construction is consistent with this embodiment, whereas Defendants' construction, as even Defendants acknowledge, (D.I. 61 at 18), would not allow for a "j-hook" type of "frangible link."

Defendants make three arguments as to why this fact does not demand the adoption of Plaintiffs' proposed construction. First, they argue that claim 4 of the '027 patent—the only claim in that patent which includes the term "frangible link"—does not cover the j-hook embodiment as illustrated in Figure 1 of the patent, because the embodiment does not include a "linkage" element required by the claim. (D.I. 61 at 18; Tr. at 75-76) Second, they note that a claim construction need not cover all embodiments. (D.I. 61 at 18 (citing *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1346 (Fed. Cir. 2005)). Third, they argue that the j-hook embodiment is found only in the '027 patent "and, thus, would apply only to 'frangible link' as used in that patent." (*Id.* at 18-19)

⁶ As to the portion of Plaintiffs' construction that requires that a frangible link becomes unlinked when a "tensile load is applied[.]" as Plaintiffs note, there is ample support for this concept in the specifications of the relevant patents-in-suit. (D.I. 57 at 23-24 (citations omitted))

As to the first two points, the Court has not been provided with much argument as to whether or not the embodiment in Figure 1 is covered by claim 4 of the '027 patent (because Figure 1 does or does not contain a “linkage”). But regardless of the correct answer to that question, the important point here is still that the '027 patent’s specification is providing the reader with a very strong statement as to what “frangible link” means. And in doing so, it is telling the reader that the term *cannot* be read as narrowly as Defendants read it. (Tr. at 80 (Plaintiffs’ counsel noting that, as to this issue, “we’re not talking about embodiments here, we’re talking about words, definitions, what is or is not a frangible link. There is no suggestion that th[e] definition, when [the '027 patent uses] the word ‘frangible link’ in this way, we’re only talking about one embodiment. *No, that is what a frangible link is.*”) (emphasis added))

As to Defendants’ third argument, Defendants are correct that the Court must determine the meaning of a disputed claim term in the context of the particular claim in which it appears, as well as the context of the particular patent at issue. *See, e.g., Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). Thus, it is possible that the Court could assign two different constructions for “frangible link”—one in the context of the '027 patent, and another in the context of the Durgin Patent. *See id.* at 1333 (recognizing that “the determination of the meaning of a particular term in one patent will not necessarily bear on the interpretation of the same term in a subsequent patent”). In *Phillips*, the Federal Circuit explained that the meaning of a claim term may not be consistent across patents in situations where “while the term is the same, the underlying factual context is different.” *Id.*

But here, the “underlying factual context[s]” of the '027 patent and the Durgin Patent are substantially similar. Both patents claim endoscopic hemostatic clipping devices, and the

respective filing dates of the patents are only a little over a year apart. Both patents came out of the same research program at Boston Scientific, and for both patents, BSSI was an applicant and is the assignee. And the patents share partially overlapping inventorship and are in other ways interrelated.⁷ (*See* '027 patent; '371 patent; Tr. at 24, 77-78). Whatever minimal differences there may be in the underlying factual contexts of the two patents, the Court has not been convinced that such differences justify different constructions of the term “frangible link” across the patents. And therefore, the '027 patent’s description of what can amount to a “frangible link” provides strong support for Plaintiffs’ construction.

3. The Prosecution History

Defendants argue that Plaintiffs disclaimed their proposed construction of “frangible link” during prosecution of the Durgin Patent. During that prosecution, the patentee argued that the Examiner had wrongly determined that what is now claim 11 (then referred to as claim 41) in the Durgin Patent was anticipated by the Adams prior art, because “there is no frangible link between any connecting element and the control wire” in Adams. (D.I. 56 at 29 (quoting D.I. 54, ex. J at COOKMED0005546); *see also* Tr. at 70-71) Thus, Defendants argue, [Plaintiffs] “conceded that the term ‘frangible link’ does not encompass the ball and socket link depicted in Figures 12A and 12B of Adams, notwithstanding the fact that it becomes unlinked when a tensile load is applied.” (D.I. 56 at 29) If this characterization of the prosecution history were accurate, it might constitute a “clear disavowal in the . . . prosecution history” sufficient to narrow the scope of “frangible link.” *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed.

⁷ Robert F. Durgin is listed as an inventor on all four patents-in-suit, and the Durgin Patent cites to parents of the asserted Adams patents.

Cir. 2004). But Plaintiffs argue, and the Court agrees, that Defendants misstate the nature of the prosecution history.

In the portion of the prosecution history cited by Defendants, the “connecting element” appears to be the ball at the end of the control wire, as the ball connects the control wire to the clip. (*See* D.I. 54, ex. J at COOKMED0005545-46) In those figures, Plaintiffs stated that “the ball 1202 remains attached to the control wire 1207 at all times and *is never separated from the control wire 1207* before or after the release of the clip[.]” (D.I. 54, ex. J at COOKMED0005545-46) (emphasis added)) In other words, the patentee was not arguing that the embodiment depicted in Figures 12A and 12B in the Adams prior art did not implicate a “frangible link” because the figures depicted “a link between two components that become unlinked when a tensile load is applied” (i.e., what is now Plaintiffs’ proposed construction for “frangible link”). Instead, Plaintiffs were arguing that Figures 12A and 12B did not depict the requisite “frangible link” because, pursuant to claim 11, “the control element *detaches from* the connector element via a frangible link”—and yet in Figures 12A and 12B, the control element *does not detach* from the connector element (the ball connector) at all. (Tr. at 81-82)⁸ Thus, Plaintiffs did not disclaim their current construction in the prosecution history of the Durgin Patent.

4. Conclusion

⁸ Nor does the Court agree with Defendants that this conclusion renders suspect the Court’s earlier assertion that, in the Durgin Patent, the yoke at issue could constitute a part of the “connector element.” (Tr. at 84) Instead, the Court agrees with Plaintiffs that while the Durgin Patent was clearly discussing a ball connector that pulled out of a “yoke” element, in the ’027 patent, it does not appear that the ball connector is pulling out of a similar “yoke” that one could assert is part of a “connector element.” Instead, in that patent, the ball appears to be pulling out of the clip. (Tr. at 77-78)

The Court will adopt Plaintiffs' proposed construction, which is not disclaimed in either the specification nor the prosecution history, and in fact finds support in the claim language and the patent specifications. The Court thus recommends construing the term "frangible link" as "a link between at least two components that become unlinked when a tensile load is applied."

C. "an opening formed in a proximal end thereof" / "an opening at a proximal end of the capsule"

The term set at issue here appears in independent claim 1 and dependent claim 15 of the Durgin Patent. Each of these claims requires a "capsule" housing the clip assembly, with either "an opening formed in a proximal end thereof[.]" ('371 patent, col. 16:63-64) (claim 1), or "an opening at a proximal end of the capsule." (*Id.*, col. 18:4, 27-30) (claim 15). In proposing the construction "a hole in the sidewall of the capsule in/at the proximal end of the capsule[.]" Defendants argue that the terms only refer to an opening in the sidewall of the capsule. (D.I. 56 at 23) Plaintiffs, on the other hand, by proposing that the terms be given their plain and ordinary meaning, assert that they may also refer to the opening at the open end of the cylindrical capsule. (D.I. 57 at 18; *see also* D.I. 56 at 24)

Defendants identify several phrases in the relevant claims that, they suggest, indicate that the "opening" has to refer to something other than "the open end of a hollow cylindrical capsule[.]" (D.I. 56 at 24) For example, Defendants note that claim 1 requires the opening to be "formed" in the proximal end of the capsule, ('371 patent, col. 16:64), and recites "a tab on the distal end of the bushing *engaging* the opening of the capsule[.]" (*id.*, col. 17:6-7) (emphasis added). Similarly, they note that claim 15 recites "a bushing including a tab on a distal end thereof *received* in an opening at a proximal end of the capsule." (*Id.*, col. 18:28-30 (emphasis

added)) The open end of a tube, the argument goes, is not “formed” in the capsule, and does not “engage” or “receive” the tabs as recited in the claims. Further, Defendants point to dependent claims 2 and 16, which describe the opening at issue as “substantially A-shaped[,]” (’371 patent, cols. 17:12-13, 18:31-32), noting that it is undisputed that the only “A-shaped” openings described in the specification are found in the sidewall of the capsule. (*See, e.g.*, ’371 patent, cols. 12:5-23, 13:38-40 & FIGS. 34-37, 40-43)

But while the claim language and the specification (including certain referenced embodiments) all certainly indicate that the claimed “opening” *may* be found in the sidewall of the capsule, there is not sufficiently strong evidence demonstrating that the term must refer *exclusively* to sidewall openings. In the Court’s view, the claims’ references to an opening being “formed” in the end of a capsule or to a tab “engaging” or being “received” in the end of a capsule do not categorically exclude an opening where the end of the capsule slides over the bushing. (D.I. 60 at 12) Moreover, as Plaintiffs rightly point out, (*id.*), the “A-shaped” limitation referred to above is found only in dependent claims 2 and 16, and since dependent claims “are, by definition, narrower than and include additional limitations as compared to the independent claims[,]” (*id.*), the wording of those claims is not dispositive here.

Beyond this, the Court notes that the plain meaning of “end” does not impose the type of narrow locational restriction suggested by Defendants here. (D.I. 61 at 15 (Defendants noting that a “sidewall” is simply one possible “element of [what] ‘end’ [might mean]”); Tr. at 104-05) With that in mind, it is important to remember that “the specification and prosecution history only compel departure from [a term’s] plain meaning in two instances: lexicography and disavowal.” *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014)

(citing *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). The patentee here did not act as its own lexicographer with regard to this disputed term, because it did not “‘clearly set forth a definition of the disputed claim term’ other than its plain and ordinary meaning.” *Thorner*, 669 F.3d at 1365 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Nor does the Court see how Defendants have met the “exacting” standard to demonstrate that the patentee clearly disavowed the plain and ordinary meaning of the term. *Id.* at 1366.

Indeed, that Plaintiffs’ position here is correct is perhaps best supported by the fact that Figures 9, 10, and 11 of the Durgin Patent appear to depict an embodiment *without* holes in the sidewall—meaning that the only “opening” therein would exist at the open end of the depicted cylindrical capsule. At the *Markman* hearing, Defendants’ counsel argued to the contrary, asserting that Figures 1-33 (including Figures 9-11) of the patent all present different views of the *same embodiment*. (See Tr. at 103-04) Therefore, according to Defendants, Figures 9, 10, and 11 necessarily depict the same embodiment as Figures 14 and 21 (which clearly do have holes in the sidewall); Defendants were suggesting that Figures 9-11 are simply pictured in such a way that their sidewall openings are obscured. (See *id.*)

However, careful inspection of the patent suggests that Defendants are not correct. When the patent describes a figure that is meant to indicate an alternate view of an embodiment depicted in a prior figure, the patent explicitly states this. But the patent describes Figure 9 simply as “an embodiment[,]” and in doing so, it does not make reference to any of the embodiments previously described in Figures 1-8. (371 patent, col. 2:17-19) And while the patent explicitly states that Figures 10 and 11 are cross-sectional views of the embodiment

depicted by Figure 9, (*id.*, col. 2:20-23), the later descriptions of Figures 14 and 21 make no explicit reference to Figure 9, (*id.*, col. 2:29-30, 40-41).⁹ Thus, the Court agrees with Plaintiffs that Figures 9-11 show that the patent discloses at least one embodiment in which the claimed “opening” does not appear in the sidewall. This dooms Defendants’ proposed construction.

For the above-referenced reasons, the Court recommends that the terms “an opening formed in a proximal end thereof” / “an opening at a proximal end of the capsule” be afforded their plain and ordinary meaning—a meaning broad enough to encompass both an opening in the hole of a sidewall of the capsule and an open end of a hollow, cylindrical capsule.

D. “coupled to the sheath”

Claim 1 of the Durgin Patent recites “a bushing extending between a proximal end coupled to the sheath”¹⁰ that encloses the control wire. (*Id.*, col. 17:4-5) Defendants argue that “[t]he prosecution history easily confirms that ‘coupled to the sheath’ means ‘not slidable inside the sheath.’” (D.I. 56 at 24) For their part, Plaintiffs propose that the phrase be given its ordinary meaning, which would be “linked together, connected, or joined.” (D.I. 57 at 14; Tr. at 119)

The specification offers an important starting point as to the phrase’s meaning in the context of the patent, and so the Court will begin there. The specification explains that the bushing and the sheath are “securely connected[.]” (’371 patent, col. 8:60-61) However, it also demonstrates that structures that are “coupled” to other structures may slide within each other, at

⁹ In the specification, moreover, Figure 14 is later referred to simply as “one exemplary embodiment[.]” (’371 patent, col. 8:50-51)

¹⁰ “Sheath” itself is a disputed term that is addressed below. There is no dispute, however, that the sheath encloses the control wire. (*See* D.I. 56 at 11; D.I. 57 at 7)

least to some degree. For example, claim 1 recites “a distal end [of a bushing] coupled to the capsule[,]” (*id.*, col. 17:4-5), while the specification describes an “exemplary embodiment [in which] the proximal end of the capsule **200** slides over the distal end of the bushing **202**[.]” (*id.*, col. 7:4-6). This indicates that the term “coupled,” as used in the patent, does not necessarily imply that the coupled elements are not “slid[able]” relative to one another. In a vacuum, this intrinsic evidence would militate in favor of Plaintiffs’ proposal. But in this case, the prosecution history suggests a different outcome.

The critical portion of the prosecution history is, once again, related to Plaintiffs’ attempt to distinguish the Durgin Patent from the Kimura reference. During prosecution, the Examiner initially rejected the claim containing the phrase “coupled to the sheath” as anticipated by Kimura. (*See* D.I. 54, Ex. J, at COOKMED0005546) Plaintiffs responded by arguing that “Kimura does not teach or suggest a bushing having ‘a proximal end coupled to the sheath[.]’” (*Id.* at COOKMED0005547) Kimura included a “hook section 12” that the Examiner “analogize[d] . . . to the claimed bushing.” (*Id.*) But Plaintiffs argued that in Kimura:

hook section 12 is not coupled to the sheath at all and in fact is *slidable inside the sheath* . . . the hook section 12 . . . must be movable relative to the sheath or the device of Kimura will be wholly inoperable. Thus, it is unclear what the Examiner is referring to when he says that a proximal end of this hook section is coupled to the sheath.

(*Id.* (emphasis added)) By referring to the ability of Kimura’s hook section to be “slidable inside the sheath” as evidence that it is not “coupled to the sheath at all,” Plaintiffs effectively disclaimed a construction of “coupled to the sheath” that allows for sliding within the sheath. *Cf.* *N. Am. Container*, 415 F.3d at 1345; *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir.

2013).

Plaintiffs argue to the contrary, noting that they distinguished Kimura during prosecution by pointing out two *other* reasons why Kimura did not teach a bushing (in Kimura, a hook) with a proximal end that was coupled to the sheath. (See D.I. 60 at 13-14) But this is of no moment. Plaintiffs could have, and did, set forth multiple reasons why Kimura's hook section did not meet the limitations of the Durgin Patent's "bushing" limitation, *including* the fact that the hook section was "slidable inside the sheath." (D.I. 54, ex. J, at COOKMED0005546-47) Whether Kimura could have been distinguished solely on other grounds does not nullify Plaintiffs' disclaimer. *See Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007) ("[A]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well."); *see also Saffran*, 712 F.3d at 559.

At the *Markman* hearing, Plaintiffs' counsel took another tack, attempting to further clarify the difference between the hook section in Kimura and the bushing in the Durgin Patent. Plaintiffs' counsel explained that the hook's interaction with the sheath in Kimura "is like [a] pen dropping through [a] pipe. The hook has no engagement with the sheath." (Tr. at 115)¹¹ In contrast, Plaintiffs' counsel argued, the sheath and the bushing in the Durgin Patent are connected to one another, and the sheath can slide over the bushing for a "certain distance," and

¹¹ The Court has been provided with no clear evidence—at least none that has been highlighted by Plaintiffs—that the hook's interaction with the sheath in Kimura was, in fact, like a "pen dropping through [a] pipe." That assertion simply amounts to attorney argument. In fact, if anything, the figures from Kimura cited to by Plaintiffs seem to show a hook depicted that appears snug with the sheath—not one that is freely "dropping" through the sheath like a pen through a pipe. (D.I. 60 at 14)

“eventually there is some sort of locking arrangement.” (*Id.* at 117-18). In other words, Plaintiffs’ counsel now was arguing that during prosecution, the patentee may have disclaimed what Plaintiffs’ counsel referred to as a “*completely* slidable arrangement” between the bushing and the sheath, (*id.* at 117), but that the patentee did not disclaim any “slidable arrangement” *per se*.

This argument is unavailing. Instructive is *North American Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335 (Fed. Cir. 2005). There, “the applicant distinguished his invention from [a prior] patent on the basis of the latter disclosing inner walls that are ‘slightly concave.’” *N. Am. Container*, 415 F.3d at 1345. The plaintiff argued that “the applicant intended only to distinguish his invention from the prior art on the basis that the inner walls in the prior art . . . are entirely concave.” *Id.* at 1345-46. But, as the Federal Circuit explained, “[a]lthough the inner walls disclosed in the [prior art] may be viewed as entirely concave, that is not what the applicant argued during prosecution to gain allowance for his claims.” *Id.* at 1346 (citation omitted). “The inescapable consequence of such an argument is that the scope of applicant’s claims cannot cover walls that are ‘slightly concave.’ Moreover, it logically follows . . . that the scope of applicant’s claims is also limited to inner walls of the base portion with no concavity.” *Id.* at 1345.

Similarly, the patentee here did not use the phrase “completely slidable in the sheath” in its response to the Examiner. Instead, the clear meaning of the words the patentee used is that if a bushing is “slidable inside the sheath” it is not “coupled to the sheath.” (D.I. 54, Ex. J, at COOKMED0005547; *see also* Tr. at 116-19) The “inescapable consequence” of the patentee’s argument, then, is that the scope of claim 1 cannot cover a bushing that is “slidable inside the

sheath.” *N. Am. Container*, 415 F.3d at 1345.

Based on the express disavowal in the prosecution history, the Court will include reference to Defendants’ proposed restriction in the Court’s final construction. Thus, the Court recommends that “coupled to the sheath” be construed as “linked together, connected, or joined, but not slidable inside the sheath.”

E. “contacting the inner surfaces” / “to contact the first and second inner surfaces”

The “linkage” limitations of the '027 patent require that the linkage “contact[] the inner surfaces” of the clip legs. ('027 patent, cols. 15:38-43; 16:19-24, 63-64) Defendants seek to limit this phrase to require the linkage to be “physically connected to [or] to physically connect to the inner surfaces of the clip legs.” (D.I. 56 at 19 (certain brackets omitted)) Plaintiffs argue that the phrase should be afforded its plain and ordinary meaning, (*id.*), which would allow embodiments in which the linkage merely “touches” the inner surfaces of the clip legs without being continuously connected.

Defendants’ argument is based on the fact that “the only ‘linkage’ described in the specification is the ‘flexible linkage 1002’ used to draw the clip legs toward one another as the control wire 1006 is pulled proximally.” (D.I. 56 at 19 (citing '027 patent, cols. 8:60-9:25)) In this embodiment (depicted in Figures 10A and 10B of the patent), Defendants assert that the flexible linkage “[has to] be *physically connected* to the clip legs—otherwise, the device would not work” (*Id.* (emphasis in original))

Plaintiffs seem to dispute Defendants’ assertion as to how this embodiment operates, (*see* D.I. 60 at 10 n.7), but the Court need not engage in an analysis of whether the referenced

embodiment requires a physical connection or not. Plaintiffs are unassailably correct (and indeed, Defendants do not really dispute) that “[c]ontacting’ is a commonly understood word that means ‘touching[.]’” or at least is a word that, on its face, does not necessarily *require* more than “touching.” See, e.g., *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111, 1124 (Fed. Cir. 2001) (“In the absence of a special definition of the term ‘contact’ in the specification, that term should be given its ordinary and accustomed meaning[, which is] ‘touching.’”); *Becton, Dickinson & Co. v. Inverness Med. Tech., Inc.*, 176 F. Supp. 2d 258, 269 (D. Del. 2001) (adopting “‘the coming together or touching of two objects or surfaces’” as the plain meaning of “‘contacting’”). As stated repeatedly at other points above, the fact that a single embodiment might incorporate a particular limitation (e.g., something more than “touching”) does not demand that a construction of the term in question requires incorporation of that restriction. *GE Lighting*, 750 F.3d at 1309. The claims at issue mandate only that the recited linkage “contact” the inner surfaces, not that it be “physically connected” to them.¹² The Court therefore recommends that “contacting the inner surfaces” / “to contact the

¹² Defendants also argue that the linkage described in the specification “must be *physically connected* to the clip legs – otherwise, the device would not work (*i.e.*, without a physical connection but only a mere touching, pulling on the control wire 1006 would not result in pulling on the flexible linkage 1002, or drawing the clip legs together.” (D.I. 56 at 19 (emphasis in original))

But claim 1 of the '027 patent, which recites a “linkage contacting the inner surfaces” of the clip legs, does not require pulling the control wire proximally to draw the clip legs together. (See '027 patent, col. 15:33-45) Rather, that claim requires only that the linkage helps spread the clip legs apart from one another “as the control member is moved *distally* relative to the clip.” (*Id.*, col. 15:38-45) Thus, it is not clear that a “linkage” that is not physically connected to the clip legs could not perform the recited function. The Court must construe the phrase “contacting the inner surfaces” to also apply to its use in claim 1, which does not appear to require a “physical connection” of the kind Defendants propose.

first and second inner surfaces” should be afforded their plain and ordinary meaning.

F. “engaging inner walls”

Each of the claims from the '731 patent that recites an “opening element” requires said element to be “engaging inner walls of the first and second clip arms[.]” ('731 patent, cols. 15:45-46, 16:32-33, 17:4-5) Plaintiffs propose that the phrase “engaging inner walls” should be afforded its plain and ordinary meaning, while Defendants propose that the phrase be construed as “physically connected to inner walls[.]” (D.I. 54 at 15) The parties’ arguments here are essentially the same as their arguments regarding the “contact[ing]” term discussed above, and here the Court reaches essentially the same conclusion as it did there.

Again, the Court starts with the proposition that the plain meaning of “engaging” does not require that something be physically connected to something else in order to be “engaging” with it. That this is so is demonstrated by certain caselaw cited in Plaintiffs’ opening claim construction brief, in which courts have construed “engaging” as meaning something akin to “contacting.” (See D.I. 57 at 17 (citing *Primos, Inc. v. Hunter’s Specialties, Inc.*, 451 F.3d 841, 847-48 (Fed. Cir. 2006) (affirming construction of “engaging” as meaning “to come into contact with”); *Stairmaster Sports/Med. Prods., Inc. v. Groupe Procycle, Inc.*, 232 F.3d 909, 2000 WL 286066, at *2-3 (Fed. Cir. Mar. 15, 2000) (affirming construction of “engaged” and “engaging” as meaning “any type of mechanical engagement capable of coming into contact, interlocking, or meshing [two separate components]”)) Of course it is true, as Defendants note, that in these cases, the factual context surrounding the relevant patents’ use of the term “engaging” was different than it is here. (See D.I. 61 at 15) But the larger point is simply that these cases help underscore that, absent clear indication in a patent to the contrary, “engaging” is

not a term that *requires* a physical connection of the kind Defendants suggest.

Defendants point to Figures 15A-D and the corresponding descriptions from the specification to argue that the “*only* disclosure in the Adams specification of corresponding structure for the claimed functions” requires a physical connection between the opening element and the inner walls. (D.I. 56 at 22-23 (citing '731 patent, col. 11:37-59 & FIGS. 15A-D)) Again though, even assuming *arguendo* that the embodiment depicted in Figures 15A-D does require Defendants’ suggested physical connection, Defendants have not offered evidence of any lexicography or disavowal of the plain meaning of “engaging” that would justify limiting the construction of the term to a single embodiment.¹³

The Court thus recommends that “engaging inner walls” be afforded its plain and ordinary meaning.

G. “a sheath”

The final disputed term is “a sheath,” which appears in claims 1 and 29 of the '048 patent and claims 1 and 11 of the Durgin Patent. Plaintiffs propose that “a sheath” means “one or more components that enclose the control wire[.]” (D.I. 56 at 11), while Defendants propose that it means “one or more components of the delivery device that enclose the control wire and that separate from the clip upon release of the control wire[.]” (*id.*).

As a starting point, the proposed constructions highlight that there is no dispute that a “sheath” amounts to “one or more components” that “enclose the control wire.” And there is

¹³ Defendants’ proposed construction also runs the risk of reading certain embodiments out of the patent. At least one drawing appears to show an “opening element” that engages inner walls without appearing to require a physical connection to them. (See '731 patent, FIG. 8A)

plenty of support in the patents for this aspect of both sides' proposed constructions. (*See* D.I. 57 at 7-8 (citations omitted))

However, Defendants' proposed construction requires the "sheath" to refer to elements of the delivery device, and it would not allow any part of the sheath to remain at the target site after deployment of the clip. Plaintiffs' proposed construction, on the other hand, would allow for embodiments in which part of the sheath may stay unseparated from the clip upon deployment.

1. The Claim Language

Defendants correctly point out that "the claims never refer to any element of the clip . . . as a 'sheath[,]'" and that components of a clip and a sheath are explicitly recited separately. (D.I. 56 at 12) Indeed, the language used in the claims indicates that the sheath is a component of the delivery device, and that a sheath is a thing that is identifiably distinct from a clip. (*See* '048 patent, cols. 15:33-36 (describing a "clip" and a "sheath" as different elements of the claimed medical device), 18:15 (noting how the "clip" is "draw[n] . . . into the sheath"); '371 patent, col. 18:17-19 ("the distal end of the sheath is releasably coupled to the capsule").

However, while the patent claims are clear that a sheath and a clip are different things, it is worth noting that Plaintiffs' proposed construction, on its face, does not necessarily imply that the sheath is a *component of* the clip. Rather, Plaintiffs' construction is such that it simply allows for a portion of the sheath to remain *attached to* the clip after deployment to a target site. Nothing in the claim language precludes such an arrangement.

Indeed, as to that issue, some of the claim language actually appears to cut directly against Defendants' proposed construction. Certain claims expressly recite the limitation sought by Defendants (that the sheath is meant to separate from the clip upon release of the control

wire), while others are silent on that point. (*Compare* '371 patent, col. 18:17-19 (requiring that “the distal end of the sheath is *releasably* coupled to the capsule” (emphasis added)), *with* '048 patent, col. 15:36 (requiring merely “a sheath enclosing the control wire”); Tr. at 182) Absent indication to the contrary in the specification or in the prosecution history, there would be no reason for the Court to limit the term “sheath” in such a way that a portion of the sheath could never remain connected to the clip after clip deployment.

2. The Specifications

The parties focus mainly on the '048 patent's specification, and it is helpful regarding these issues. In that patent, in both the written description and corresponding drawings, the sheath is consistently identified as a component of the delivery device that is distinct from the clip. (*See, e.g.*, '048 patent, cols. 5:31-32 (“The control wire **108** is enclosed within sheath **111**”), 9:50-56 (describing an “outer sleeve . . . attached by way of a breakaway connection . . . to the sheath” that releases from the sheath “with the clip”), 10:15-58 (describing an embodiment in which the sheath is part of the delivery device and releases from the clip), 12:45-51 & FIG. 18F (depicting an embodiment in which “the clip is housed in the end of a sheath” and separates upon deployment), 13:38-51 (noting that “the clip **2001** and inner sleeve **2004** are released from the sheath” and that the delivery device consists of a sheath)).

On the other hand, none of the above-referenced portions of the patent expressly exclude the possibility that a part of the sheath may remain with the clip at the deployment site. Indeed, when discussing the “sheath” element, the Summary of the Invention section of the '048 patent provides only for “an axially rigid sheath enclosing the control wire and communicating a compressive force opposing a tensile force of the control wire[.]” ('048 patent, col. 2:65-67)

Despite the repeated references to the clip releasing from the sheath in several embodiments, the Court is not persuaded that the patents require the limitation that no part of the sheath may ever remain with the clip at the target site.

3. Prosecution History

Defendants' final argument stems from the prosecution history of U.S. Application No. 10/674,512 (the "'512 Application").¹⁴ Specifically, Defendants assert that BSSI "attempted repeatedly to distinguish Prior Art Adams by explaining that, in Adams, *the clip separates from the sheath on deployment.*" (D.I. 56 at 12 (emphasis in original); *see also* D.I. 61 at 3) And indeed, it is true that in distinguishing the '512 Application from the Adams prior art, BSSI did note that the invention claimed by Adams involved the clip being released from the sheath. (*See* D.I. 54, ex. I at COOKMED0004422)

And yet, the distinctions that the patentee highlighted between the Adams prior art and the '512 Application were not based on any requirement that a sheath always must separate entirely from a clip, and thus do not otherwise support Defendants' proposed construction. The portion of the prosecution history on which Defendants rely addresses claim 1 of the '512 Application, which required a "ball connector . . . detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft[.]" (*Id.*) Thus, the relevant claim recited a shaft (not a sheath) from which the clip assembly separated. The patentee further argued that Adams did not anticipate the '512 Application because the Adams apparatus did not provide a first or second user feedback in the manner required by claim 1. (*See*

¹⁴ The Durgin Patent application was a continuation of the '512 Application, and expressly incorporated by reference the entire disclosure of the '512 Application.

id.; *see also* D.I. 60 at 3-4) While the patentee did explicitly acknowledge that at least one embodiment of Adams involves a release of the clip from the sheath, it did not clearly indicate that a portion of the sheath could never remain with a clip after a clip was deployed.

4. Conclusion

For the foregoing reasons, the Court recommends that “a sheath” be construed as “one or more components of the delivery device that enclose the control wire.”

IV. CONCLUSION

For the foregoing reasons, the Court recommends the following constructions:

1. “a control element including a connector element” should be afforded its plain and ordinary meaning.
2. “frangible link” means “a link between at least two components that become unlinked when a tensile load is applied.”
3. “an opening formed in a proximal end thereof” / “an opening at a proximal end of the capsule” should be afforded their plain and ordinary meaning.
4. “coupled to the sheath” means “linked together, connected, or joined, but not slidable inside the sheath.”
5. “contacting the inner surfaces” / “to contact the first and second inner surfaces” should be afforded their plain and ordinary meaning.
6. “engaging inner walls” should be afforded its plain and ordinary meaning.
7. “a sheath” means “one or more components of the delivery device that enclose the control wire.”

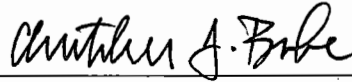
This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R.

Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation.

Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>.

Dated: December 22, 2016



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE